SUPERIOR COURT OF NEW JERSEY
APPELLATE DIVISION
DOCKET NO. A-1501-23

ALISON BEAVAN,

Plaintiff-Respondent,

v.

ALLERGAN U.S.A., INC.,

Defendant-Appellant,

and

ALLERGAN INC., f/k/a INAMED CORPORATION, ALLERGAN PLC, and ABBVIE INC.,

Defendants.

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Argued November 14, 2024 – Decided November 21, 2024

Before Judges Mawla and Vinci.

On appeal from an interlocutory order of the Superior Court of New Jersey, Law Division, Morris County, Docket No. L-0151-21.

Daniel B. Rogers (Shook, Hardy & Bacon, LLP) of the Florida bar, admitted pro hac vice, argued the cause for

appellant (Schenck Price Smith & King, LLP, and Daniel B. Rogers, attorneys; Timothy I. Duffy and Jonathan F. Donath, on the briefs).

Thomas S. Alch and Dennis M. Donnelly argued the cause for respondent (The Donnelly Law Firm, LLC, attorneys; Dennis M. Donnelly, on the brief).

Natalie H. Mantell argued the cause for amicus curiae Healthcare Institute of New Jersey and New Jersey Business & Industry Association (McCarter & English, LLP, attorneys; Natalie H. Mantell, of counsel and on the brief; Leroy E. Foster, on the brief).

Reed Smith, LLP, and Barnes & Thornburg, LLP, attorneys for amicus curiae The Product Liability Advisory Council, Inc., and the Chamber of Commerce of the United States of America (Melissa Geist, Michael C. Zogby, and Kaitlyn Stone, on the brief).

PER CURIAM

We granted defendant Allergan U.S., Inc. leave to appeal from: two orders entered on May 26, 2023, denying its motions for summary judgment and to bar plaintiff Alison Beavan's experts; and a November 13, 2023 order denying defendant's motion for reconsideration. Having considered the record on appeal, we affirm in part and reverse in part, for the reasons expressed in this opinion.

Plaintiff had a history of various eye diseases, including non-infectious chronic uveitis and cystoid macular edema. She also suffered from chronic eye inflammation and was a smoker, which caused additional inflammation.

In July 2015, plaintiff became a patient of the Retinal Group of Washington under the care of Dr. William Phillips, a retina specialist and vitreoretinal surgeon. She received treatments over the course of three years, including ten injections of Ozurdex in both eyes, a trabeculectomy, two vitrectomy procedures, a silicone coated Retisert tablet implant, which later became dislocated, and had a right eye cataract extraction.

This appeal concerns Ozurdex, a prescription drug manufactured by defendant to treat various eye diseases, including non-infectious uveitis. It is a dexamethasone implant (pellet) preloaded in a single-use applicator, which is injected into the vitreous of the eye.

On November 6, 2018, Dr. Phillips administered an Ozurdex injection into plaintiff's left eye from Ozurdex Lot #E82852. A week later, plaintiff returned to his office with new complaints of severe left eye blurred vision, decreased vision, and a blind spot. Dr. Phillips diagnosed plaintiff with retinal detachment. The following day, he performed a pars plana vitrectomy on plaintiff's left eye to treat the retinal detachment. Plaintiff was referred to a cornea specialist, Dr. Jonathan D. Solomon, who diagnosed her with corneal degeneration, secondary to a contaminated pellet injection in the left eye.

On June 21, 2018, defendant became aware that "[d]uring a routine manufacturing inspection, a silicone particulate, approximately 300 microns in diameter, was observed in dispensed Ozurdex implants." Those inspection results were memorialized in a July 2018 Initial Nevada Field Alert. By mid-September 2018, defendant began recalling certain Ozurdex lots in foreign countries where affected lots were distributed and reported the Nevada Field Alert inspection results to the Food and Drug Administration (FDA).

At that time, defendant knew the defect existed in 2.2% of the units contained in Ozurdex Lot #E82852. Defendant nonetheless distributed that lot and twenty-one others to patients in consideration of drug shortage directives issued by the FDA.

On October 3, 2018, defendant submitted a draft Dear Health Care Provider (DHCP) letter to the FDA for approval to inform physicians of its findings regarding the affected lots. The letter advised of the potential product defect, the clinical implications, and that "extra-vigilance on behalf of clinicians and patients is required." According to defendant's epidemiology and FDA expert, before plaintiff received her injection, defendant had made "over [twenty] attempts to obtain authorization from [the] FDA to communicate [with] U.S. healthcare providers about the silicone particulate issue." On October 17,

2018, the FDA advised defendant that it believed the defect was "not a safety concern[,]" but a "product quality" issue. As a result, defendant did not issue the DHCP letter. Nonetheless, the FDA recommended defendant "address the problem."

On December 28, 2018, defendant issued an urgent drug recall of Ozurdex in the United States with FDA approval, which included Lot #E82852. The reason for the recall was the possibility of a silicone particulate discharge when dispensed with the unit. The recall notice advised the health hazards associated with the defective product were: "mild transient visual disturbance or intraocular inflammatory reaction in sensitive patients[;] . . . corneal reaction if the particulate migrates to the anterior chamber[;]" and "overall risk probability is considered low." Defendant conducted a study of Ozurdex on animal subjects between January and October 2019, which found "no abnormal findings related to the silicone particles in the . . . eyes by ocular, ophthalmic, intraocular pressure, or histopathologic examination."

Dr. Phillips became aware of the recall in early 2019 and discussed the matter with plaintiff on January 15, 2019. Prior to her final Ozurdex injection, plaintiff's vision was 20/100. By February 1, 2019, she was blind in her left eye.

On November 5, 2020, plaintiff filed a complaint against defendant[1] alleging: negligence; strict products liability under the New Jersey Products Liability Act (PLA), N.J.S.A. 2A:58C-1 to 11; and breach of implied warranty. She sought damages for the complete loss of vision in her left eye, which she attributed to a dose of Ozurdex that was manufactured by defendant.

The PLA count alleged defendant's product "was defective and dangerous, both in warning, manufacture and in design, thereby rendering [it] unsafe for its intended use and that the defects were a direct and proximate cause of the injury." Defendant's answer denied liability and asserted various defenses, including that plaintiff's claims were preempted by the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301.

Plaintiff offered expert testimony from Dr. Maziar Lalezary, a Board-Certified Ophthalmologist and a Vitreo-Retinal Surgical Fellow, who opined the silicone particulate proximately caused plaintiff's injuries. She also designated Dr. Phillips to testify regarding causation. Like Dr. Lalezary, he opined the silicone particulate proximately caused plaintiff's injuries.

Defendant moved for summary judgment on the PLA count and to bar plaintiff's expert opinions as net opinions. It argued the court should dismiss

[1] The other named defendants are not a part of this case.

the complaint because there was no evidence the Ozurdex applicator had a manufacturing defect or that a silicone particulate ever entered plaintiff's eye. Defendant also sought summary judgment because its alleged failure to timely warn of a recall was preempted as a matter of law.

Defendant's motion to bar the experts argued they each failed to provide a reliable basis to support their opinions that the silicone particulate could cause inflammation, retinal detachment, corneal damage, or loss of vision. The experts failed to show the Ozurdex unit administered to plaintiff contained a silicone particulate that caused her injuries. Also, the experts were unqualified to opine about how defendant should have warned doctors about the risk of silicone particulate associated with the Ozurdex recall.

Following oral argument, the trial court issued the May 26, 2023 orders accompanied by written opinions denying defendant's motions. It found a dispute of material facts because plaintiff's experts opined the Ozurdex "was defective with a silicone particulate that proximately caused [p]laintiff's injuries . . . ." The court noted Dr. Lalezary opined "the particulate caused inflammation and traction in [plaintiff's] peripheral retina that induced a retinal break and led to her retinal detachment. And subsequently, she had detachment repair that led to the anterior migration of the Ozurdex pellet." The doctor opined plaintiff's

vision was compromised "because a patient with uveitis that develops a retinal detachment has a poor prognosis for recovery and vision."

The court also noted plaintiff "present[ed] testimony from [d]efendant's . . . expert that the disbursement of a silicone particulate would deviate from [defendant's] own performance standards for the product, and that the Ozurdex applicator was not designed to dispense a silicone particulate with the . . . medication." This supported a theory of liability under a deviation from design specifications or manufacturer performance standards pursuant to N.J.S.A. 2A:58C-2.

Dr. Phillips' testimony also created a dispute of material facts because he opined the silicone particulate would cause an inflammatory response. In plaintiff's case, the inflammatory response "persisted even long after the Ozurdex implant itself was gone." Dr. Phillips noted plaintiff had "multiple injections before . . . and . . . never had this much inflammation, despite the fact that she does have uveitis. So something was just different this time to cause that much inflammation . . . ." The court concluded "Dr. Phillip[s] clearly . . . opined . . . the alleged particulate created persistent inflammation in [p]laintiff's eye that proximately caused her injuries."

The trial court held plaintiff's experts did not offer net opinions because their opinions were "sufficiently based in fact and data to be admissible under N.J.R.E. 703." Although both experts conceded there was no objective evidence that a silicone particulate existed, the PLA did not require direct evidence of a product defect and circumstantial evidence of a defect was enough. The court noted plaintiff's experts based their opinions "in part, on the fact . . . [p]laintiff had received nine Ozurdex injections with no complications prior to the November 6, 2018 procedure, and that the only variable and most likely explanation for the complications arising after the November 6 . . . procedure is that the Ozurdex applicator was from a defective lot." Thus, there was a sufficient basis for plaintiff's experts to conclude there was no direct evidence of the particulate because both plaintiff and defendant's experts agreed "the particulate could have been aspirated out or remain[ed] hidden in scar tissue in [p]laintiff's eye . . . ." The trial court concluded "[t]herefore, . . . the lack of 'objective evidence' goes to the weight of [p]laintiff's expert's testimony, not its admissibility."

The court held plaintiff's experts could opine the silicone particulate could have caused retinal detachment because their opinions were based on the direct and circumstantial evidence in the summary judgment record, including:

"plaintiff's medical records; deposition transcripts; and defendant's risk assessment, field alerts, worldwide and domestic recalls, [and] package inserts regarding the risks of Ozurdex . . . ." Further, it was not reasonable to conclude plaintiff's experts offered a net opinion "when [d]efendant's own recall contained those very same warnings of intraocular inflammatory reaction and corneal reaction as potential safety risks." Defendant was not entitled to summary judgment due to the totality of the evidence and because plaintiff was "only required to show that the alleged product defect proximately caused or was a substantial factor in causing her injuries . . . ." The court concluded plaintiff had "presented sufficient evidence of a manufacturing defect and admissible expert opinion that such defect proximately caused [her] injuries to create a dispute of material fact."

Defendant moved for reconsideration, reiterating the arguments raised in the summary judgment motion. It asserted there was no: evidence of a silicone particulate in the Ozurdex treatment plaintiff received on November 6, 2018; evidence particulate entered plaintiff's eye; reliable methodology proffered by an expert showing there was a manufacturing defect and Dr. Phillips was unqualified to testify about the manufacturing process; circumstantial evidence of a manufacturing defect; and expert evidence on causation either in general or

specific. It also argued the court should have dismissed the second count of plaintiff's complaint, which was the failure to recall the claim, because it was not a viable cause of action under the PLA and the PLA preempted the claim.

The trial court again rejected defendant's arguments. It found plaintiff presented "sufficient evidence . . . to survive a motion for summary judgment . . . [and] create a dispute of material fact as to whether the alleged defect (i.e., the silicone particulate) proximately caused [p]laintiff's injuries, and any other inconsistencies of fact [are] best reserved for a jury to contemplate." The court rejected the argument it erred by not dismissing the failure to warn claim because the PLA claim was indivisible. Therefore, "[i]f the [c]ourt followed [d]efendant's reasoning, [it] would strike [p]laintiff's request for relief under the PLA altogether."

The trial court rejected defendant's challenges on the issue of lack of expert evidence regarding causation and net opinion. It found defendant presented no law or facts that the court overlooked and reiterated "that Dr. Lalezary's and Dr. Phillip[s] opinion[s] were sufficiently based in fact and data to be admissible under N.J.R.E. 703." Although both "experts admitted that there is no 'objective evidence' that a silicone particulate existed, direct evidence of a product defect is not required under the PLA to show a product defect

existed." (citing Scanlon v. Gen. Motors Corp., Chevrolet Motor Div., 65 N.J. 582, 592-93 (1974)). The court reiterated a product defect could "be demonstrated through 'circumstantial evidence and the facts shown,' which [it] previously found in this matter." It rejected the lack of causation argument because "[s]ufficient expert testimony [was] shown to create an issue of material fact as to whether the defective Ozurdex applicator proximately caused [p]laintiff's injuries."

I.

Our review of a ruling on summary judgment is de novo, applying the same legal standard as the trial court. Townsend v. Pierre, 221 N.J. 36, 59 (2015). "Summary judgment must be granted if 'the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show . . . there is no genuine issue as to any material fact challenged and that the moving party is entitled to a judgment . . . as a matter of law.'" Town of Kearny v. Brandt, 214 N.J. 76, 91 (2013) (quoting R. 4:46-2(c)). We consider whether "the competent evidential materials presented, when viewed in the light most favorable to the non-moving party, are sufficient to permit a rational factfinder to resolve the alleged disputed issue in favor of the non-moving party." Ibid. (quoting Brill v. Guardian Life Ins. Co., 142 N.J. 520, 540 (1995)).

When reviewing an order denying reconsideration, we apply an abuse of discretion standard. Fusco v. Bd. of Educ. of City of Newark, 349 N.J. Super. 455, 462 (App. Div. 2002). The standard is inherently deferential. Pitney Bowes Bank, Inc. v. ABC Caging Fulfillment, 440 N.J. Super. 378, 382 (App. Div. 2015).

We accord no deference to the trial court's conclusions on issues of law and review those issues de novo. Nicholas v. Mynster, 213 N.J. 463, 478 (2013). "Preemption determinations are reviewed de novo, as are the issues of statutory interpretation necessary to the preemption inquiry." In re Alleged Failure of Altice USA, Inc., 253 N.J. 406, 415 (2023) (citing In re Reglan Litig., 226 N.J. 315, 327 (2016)).

II.

Defendant argues the trial court should have dismissed the failure to recall claim because it was subsumed into the strict products liability count of plaintiff's complaint and preempted by the FDCA and its regulation, 21 C.F.R. §§ 7.40 to 7.59. It asserts FDA regulations for prescription drug recall impliedly preempt the PLA "failure to warn" law for the manufacture and distribution of prescription drugs that are approved by the FDA and later subject to recall. Therefore, defendant's compliance with FDA regulations shields it from liability

for injuries attributable to defective FDA approved drugs. Defendant claims its preemption argument pertained to federal law and the trial court misunderstood the issue as preemption under the PLA.

Amici, the Product Liability Advisory Council, Inc. and the Chamber of Commerce of the United States of America, join in defendant's preemption argument and its argument that a failure to recall claim is not cognizable under the PLA. Amici, the Healthcare Institute of New Jersey and New Jersey Business & Industry Association, argue the court's decision "disrupt[s]" the PLA.

The trial court did not squarely address federal preemption. Our Supreme Court recently stated that preemption analysis begins with the assumption that state police powers are not to be disturbed unless clearly preempted by Congress through federal legislation pursuant to the Supremacy Clause of the United States Constitution, Article VI, Clause 2. See Altice, 253 N.J. at 416 (citing Altria Grp., Inc. v. Good, 555 U.S. 70, 77 (2008)); see also Dewey v. R.J. Reynolds Tobacco Co., 121 N.J. 69, 77 (1990). The essential question for any preemption analysis is "whether Congress intended that the federal regulation supersede state law." Dewey, 121 N.J. at 77-78 (citing La. Pub. Serv. Comm'n v. Fed. Commc'ns Comm'n, 476 U.S. 355, 369 (1986)). "Ordinarily, state causes

of action are not pre-empted solely because they impose liability over and above that authorized by federal law." Feldman v. Lederle Lab'ys, a Div. of Am. Cyanamid Co., 125 N.J. 117, 136 (1991) (Feldman II) (citations omitted).

Federal law can preempt state laws expressly, impliedly, or through conflict. Altice, 253 N.J. at 417. Implicit preemption exists when the "'federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the State to supplement it,' . . . or when the 'object sought to be obtained by federal law and the character of the obligations imposed by it may reveal the same purpose.'" Dewey, 121 N.J. at 77-78 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)); see also Altice, 253 N.J. at 417 (describing implicit preemption as "field preemption"). Field preemption requires the court to assess through inference or Congressional silence how pervasive federal laws were intended to preempt state police power. Altice, 253 N.J. at 417.

The question on this appeal is whether the failure to warn strict liability claim asserted pursuant to the PLA is preempted by the FDCA's regulatory scheme. The FDA is charged with the control and supervision of numerous consumer products, including prescription drugs. 21 U.S.C. § 355(d); Merck Sharp & Dohme Corp. v. Albrecht, 587 U.S. 299 (2019). All FDA regulations

are mandated by the FDCA. 21 U.S.C. §§ 301 to 399. The FDCA prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded." 21 U.S.C. § 331(a). In enacting the FDCA, Congress's primary concern was to protect consumers from unsafe drugs and fraudulent marketing. Wyeth v. Levine, 555 U.S. 555, 566 (2009).

In the case of prescription drugs, the FDA's role is both broad and nuanced. It includes initial testing and approval of drugs for sale in the United States, 21 C.F.R. § 314.105,[2] in addition to monitoring its continued safety and managing recalls thereafter, when necessary, 21 C.F.R. §§ 7.40 to 7.59.

Generally, drug manufacturers seek advance FDA permission to make substantive changes to their drug labels. Albrecht, 587 U.S. at 304. The FDA requires that any "major changes" to an NDA be submitted and approved by it, 21 C.F.R. § 314.70(b), while only certain "moderate changes" may require FDA approval, 21 C.F.R. § 314.70(c).[3] However, prior FDA approval is not required

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[2] The "FDA will approve [a new drug application (NDA)] after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling . . . ." 21 C.F.R. § 314.105.

[3] 21 C.F.R. § 314.70 is known as the "'changes being effected' (CBE) regulation . . . ." Wyeth, 555 U.S. at 568.

in cases where the manufacturer seeks to "add or strengthen a contraindication, warning, precaution, or adverse reaction" to the labeling. 21 C.F.R. § 314.70(c)(6)(iii)(A). "For that reason, . . . 'clear evidence' that the FDA would not have approved a change to the drug's label prempts a claim, grounded in state law, that a drug manufacturer failed to warn consumers of the change-related risks associated with using the drug." Albrecht, 587 U.S. at 302-03 (citing Wyeth, 555 U.S. at 571).

Communications from manufacturers to health care providers advising of updates on important, new, or updated product information can also be managed through DHCP letters. These letters constitute "labeling" under the FDCA. See R.F. v. Abbott Lab'ys, 162 N.J. 596, 626 n.18 (2000) ("Those alternative methods of warning the [t]est's users suggested by plaintiffs clearly constitute 'labeling' under the FDCA."); see also Kordel v. United States, 335 U.S. 345, 349 (1948) (stating "the boundaries of the prohibited action would then be defeated" should the FDCA be interpreted to differentiate how and where the drug labeling literature is distributed).

Federal regulations interpreting the mandates of the FDCA also detail recall procedure and obligations for prescription drugs in 21 C.F.R. Ch. I, Subch. A, Pt. 7 "Enforcement Policy." The FDA's recall regulation provides:

(a) Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the [FDA]. Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. This section and §§ 7.41 through 7.59 recognize the voluntary nature of recall by providing guidance so that responsible firms may effectively discharge their recall responsibilities. These sections also recognize that recall is an alternative to a [FDA]-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the [FDA] to monitor recalls and assess the adequacy of a firm's efforts in recall.

(b) Recall may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the [FDA]. A request by the [FDA] that a firm recall a product is reserved for urgent situations and is to be directed to the firm that has primary responsibility for the manufacture and marketing of the product that is to be recalled.

(c) Recall is generally more appropriate and affords better protection for consumers than seizure, when many lots of product have been widely distributed. Seizure, multiple seizure, or other court action is indicated when a firm refuses to undertake a recall requested by the [FDA], or where the agency has reason to believe that a recall would not be effective, determines that a recall is ineffective, or discovers that a violation is continuing.

[21 C.F.R. § 7.40.]

Recall measures can be initiated by the FDA and the manufacturer. 21 C.F.R. §§ 7.45 and 7.46. "Firm-initiated recall" provisions autonomously permit manufacturers the authority to remove or correct a defective product prior to FDA recall review and approval. The relevant regulation states:

> (a) A firm may decide of its own volition and under any circumstances to remove or correct a distributed product. A firm that does so because it believes the product to be violative is requested to notify immediately the appropriate [FDA] district office . . . . Such removal or correction will be considered a recall only if the [FDA] regards the product as involving a violation that is subject to legal action, e.g., seizure.
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> . . . .
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> (b) The [FDA] will review the information submitted, advise the firm of the assigned recall classification, recommend any appropriate changes in the firm's strategy for the recall, and advise the firm that its recall will be placed in the weekly FDA Enforcement Report. Pending this review, the firm need not delay initiation of its product removal or correction.
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> [21 C.F.R. § 7.46.]

However, any attempt to enforce or restrain violations of the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337. In Cornett v. Johnson & Johnson, our Supreme Court examined the boundaries of FDA's preemption and concluded that "regardless of how a plaintiff styles a state claim, if the claim depends on the alleged violation of a federal requirement, it is

functionally equivalent to a claim grounded solely on the federal violation, and is impliedly preempted." 211 N.J. 362, 385 (2012), abrogated on other grounds by McCarrell v. Hoffmann-La Roche, Inc., 227 N.J. 569 (2017). In other words, there is no private cause of action for allegations built upon FDCA violations. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 (2001). Accordingly, there can be no private cause of action alleging failure to recall pursuant to 21 C.F.R. § 7.40. At oral argument, plaintiff confirmed she did not assert a cause of action based on a failure to recall.

Cornett involved a failure to warn claim under the PLA that was expressly preempted by the Medical Devices Amendments of 1976 (MDA)[4]. 211 N.J. at 390-91. The Court explained the FDA is vested with exclusive authority to enforce a delicate and robust regulatory scheme created by Congress and "[a] fraud-on-the-FDA claim has the potential to interfere with this delicate balance." Id. at 390. Therefore, failure to warn claims based on FDA violations are impliedly preempted by 21 U.S.C. § 337. Ibid. The Cornett Court held:

> If discovery reveals that the failure to warn claim is nothing more than a private action to enforce FDA statutes and regulations, or that plaintiffs' claim is no

[4] "[T]he MDA expressly pre-empts only state requirements 'different from, or in addition to, any requirement applicable . . . to the device' under federal law, § 360k(a)(1)." Riegel v. Medtronic, 552 U.S. 312, 321 (2008) (omission in original).

> more than a challenge to the approval of the device or label, or that proof of fraud on the FDA is an element of their claim, or that defendants' off-label promotional activities fall within the MDA safe harbor, defendants may move for summary judgment, and the trial court should not hesitate to grant such relief, if appropriate.
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> [Id. at 391 (citing NCP Litig. Tr. v. KPMG, LLP, 187 N.J. 353, 384-85 (2006)).]

It is only when "plaintiffs' failure to warn claim is based on other allegations of wrong-doing apart from defendants' failure to comply with FDA disclosure requirements, [that] it is not preempted." Id. at 390. These State claims exist "parallel" to the federal requirements. Id. at 385 (citing Riegel, 552 U.S. at 330).

In Wyeth, the plaintiff received a dose of a prescription drug via an intravenous push, which was injected into an artery rather than a vein, leading to amputation of the plaintiff's arm. Id. at 559. The plaintiff's suit against Wyeth alleged it failed to adequately warn about the risk administering the drug via an intravenous push. Id. at 559-60. The Court held state law failure to warn claims against a drug manufacturer were not preempted by federal law specifically when applied to approved FDA drug labeling. See id. at 581. The failure to warn claim was not preempted because the manufacturer was unilaterally permitted to strengthen a drug warning based on its responsibility for post-

marketing surveillance and to update the labeling with new safety information. Id. at 573. Indeed, "the very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning pursuant to the CBE regulation is difficult to accept—neither Wyeth nor the United States has identified a case in which the FDA has done so." Id. at 570.

The Wyeth Court noted an absence of express preemption of prescription drugs in the FDCA's seventy-year history, despite "certain awareness of the prevalence of state tort litigation . . . ." Id. at 575. It concluded that Congressional inaction supported the conclusion that state lawsuits were not an obstacle to FDA objectives, and "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." Ibid.

Defendant argues the FDA's recall regulations are comprehensive and occupy the entire field, which forecloses a state from regulating prescription drug recalls. It points us to In re Human Tissue Prod.'s Liab. Litig., 488 F. Supp. 2d 430, 433 (D.N.J. 2007), and Clark v. Actavis Grp. HF, 567 F. Supp. 2d 711, 717 (D.N.J. 2008), in support of the notion the FDA intended to assume all control over monitoring recalls and recall communications. However, these cases were decided prior to Wyeth and Cornett, and we are not bound by these rulings.

Plaintiff's PLA complaint was crafted as a single count, which alleged Ozurdex was "defective and dangerous, both in warning, manufacture and in design." The complaint did not allege a failure to warn alone, but also a manufacturing defect and a failure to warn post-sale, neither of which are preempted by the FDCA.

There is a "longstanding coexistence of state and federal law and the FDA's traditional recognition of state-law remedies . . . ." Wyeth, 555 U.S. at 581. A claim alleging wrongdoing "falls within a traditional area of state concern" provided that "fraud on the FDA is not an element of the claim and it can be proved by evidence other than by evidence of fraud on the FDA." Cornett, 211 NJ. at 390.

We reject defendant's argument the FDA's uniform drug recall protocol, 21 C.F.R. § 7.40(a), shields drug manufacturers from their duty to alert the public of known unsafe and hazardous products released to the public completely. This would undermine the intent and purpose of the FDCA, which "as a whole was designed primarily to protect consumers from dangerous products." Feldman II, 125 N.J. at 148 (quoting U.S. v. Sullivan, 332 U.S. 689, 696 (1948)).

In all FDCA labeling and recall protocols there are exceptions for manufacturers to enhance their product warnings. See 21 C.F.R. § 314.70(c)(6)(iii)(A) (noting FDA approval is not required in cases where the manufacturer seeks to "add or strengthen a contraindication, warning, precaution, or adverse reaction" to the labeling). The FDCA product recall protocol does not require the manufacturer to wait for FDA approval before notifying the public of its safety concerns. A "firm may decide of its own volition and under any circumstances to remove or correct a distributed product" when it believes it to be violative. 21 C.F.R. § 7.46(a). Pending FDA recall review, "the firm need not delay initiation of its product removal or correction." 21 C.F.R. § 7.46(b). These principles are underscored by the fact that here defendant issued the DHCP alerting physicians about the defective lot of Ozurdex. There is no rational basis to conclude this was somehow in conflict with FDCA regulations.

We also reject defendant and amici's arguments that a failure to recall claim is not cognizable under the PLA regardless of preemption. Excepting the causation issue addressed in the next section, the summary judgment record contained enough evidence to support plaintiff's claim she was damaged due to

defendant's failure to warn her of the defective Ozurdex lot, which was known to defendant at the time she was injected with Ozurdex.

"Under New Jersey law[,] a manufacturer is strictly liable for damages resulting from use of its products when the manufacturer fails to produce and distribute a product that is fit, suitable, and safe for its foreseeable purposes." Feldman II, 125 N.J. at 144. In the case of a "failure to warn" claim, the Court explained:

> A manufacturer is obligated to communicate a warning based on subsequently-acquired knowledge of a danger "as soon as reasonably feasible." Feldman v. Lederle Lab'ys (Feldman I), 97 N.J. 456 (1984). "Generally speaking, the doctrine of strict liability assumes that enterprises should be responsible for damages to consumers resulting from defective products regardless of fault." Id. at 450. When liability is premised on the failure to warn or an inadequate warning, the issue becomes whether the manufacturer knew or could have known of the danger and, if so, whether it "acted in a reasonably prudent manner in marketing the product or in providing the warnings given." Id. at 451-52.
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> [Feldman II, 125 N.J. at 144.]

While manufacturers in compliance with FDA labeling requirements are entitled to a rebuttable presumption that the warning labeling was adequate,

N.J.S.A. 2A:58C-4,[5] the PLA permits a plaintiff to allege the manufacturer was aware of "after-acquired knowledge of harmful effects" and failed to disclose them in violation of the PLA.[6] Cornett, 211 N.J. at 388. As we noted, labeling includes a DHCP communication. Abbott Lab'ys, 162 N.J. at 626 n.18. Because plaintiff's failure to warn claim is based on the allegation defendant "withheld information from the general public and the medical community" regarding the distribution of defective Ozurdex lots and the potential harm the affected lots could cause patients, plaintiff's claim overcame the PLA's rebuttable presumption of warning label adequacy. Cornett, 211 N.J. at 390 (citing Perez v. Wyeth Lab'ys Inc., 161 N.J. 1, 25 (1999)).

For these reasons, the trial court correctly held the PLA claim was not preempted. Plaintiff asserted a viable PLA claim based on defendant's failure to warn patients of the product defect.

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[5] "If the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the [FDA] under the [FDCA] . . . , a rebuttable presumption shall arise that the warning or instruction is adequate." N.J.S.A. 2A:58C-4.

[6] "[W]here the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question, punitive damages may be awarded." N.J.S.A. 2A:58C-5.

III.

A.

Defendant argues the trial court erred by failing to dismiss the complaint due to plaintiff's failure to present a manufacturing expert with experience in biomaterials, biocompatibility, biomechanics, and microscopic silicone particulate to establish there was a particulate in the injection plaintiff received and therefore causation. It alleges the recall notice of the Ozurdex lot was not competent evidence to establish plaintiff was injured by a defective dose of Ozurdex. Amici, the Healthcare Institute of New Jersey and New Jersey Business & Industry Association, join in this aspect of defendant's argument.

Defendant claims plaintiff's experts offered net opinions because they could not opine about the manufacturing defect and had no idea if a particulate entered plaintiff's eye and was the cause of her injury. It asserts the trial court did not fulfill its gatekeeping role, and instead permitted evidence of the recall "and temporal association to substitute for qualified expert opinion derived from application of reliable methodology to the facts."

B.

A plaintiff may recover damages under the PLA for a: product manufacturing defect; failure to warn; or product design defect. See N.J.S.A.

2A:58C-2. "A product is deemed to be defective if it is not reasonably fit, suitable, or safe for the ordinary or foreseeable purpose for which it is sold." Myrlak v. Port Auth. of N.Y. & N.J., 157 N.J. 84, 97 (1999). In a manufacturing defect case, "a plaintiff must prove that the product was defective, that the defect existed when the product left the manufacturer's control, and that the defect proximately caused injuries to the plaintiff, a reasonably foreseeable or intended user." Ibid. This can be accomplished through "direct evidence, such as the testimony of an expert who has examined the product, or, in the absence of such evidence, to circumstantial proof." Id. at 98. A plaintiff who cannot prove a defect through direct or circumstantial evidence can do so by negating all other causes for the dangerous condition. Id. at 99.

"The law is 'settled in this State that in a products liability case[,] the injured plaintiff is not required to prove a specific manufacturer's defect.'" Id. at 98 (quoting Moraca v. Ford Motor Co., 66 N.J. 454, 458 (1975)). Evidence "that a product is not fit for its intended purposes 'requires only proof .·.·. that "something was wrong" with the product.'" Ibid. (quoting Scanlon, 65 N.J. at 591). However, "[t]he mere occurrence of an accident and the mere fact that someone was injured are not sufficient to demonstrate the existence of a defect." Ibid.

Here, no one disputes that expert testimony is required to identify the manufacturing defect alleged by plaintiff. This is because Ozurdex is the sort of product that "is so esoteric that jurors of common judgment and experience cannot form a valid judgment as to whether the conduct of the party was reasonable." Rocco v. N.J. Transit Rail Operations, Inc., 330 N.J. Super. 320, 341 (App. Div. 2000) (quoting Butler v. Acme Mkts., Inc., 89 N.J. 270, 283 (1982)).

Plaintiff's PLA claim did not rely solely on the recall of the Ozurdex lot that was administered to her. Her claim was also based on testimony from defendant's corporate representative who said the Ozurdex "applicator was not designed to release silicone particulate." There was also the Field Alert Report defendant sent to the FDA, which stated the defective units containing the silicone particulate were "intrinsic to the manufacturing process and not an external contaminant." Defendant's DHCP letter further admitted the discovery of a silicone particle dispensed with the Ozurdex implant during a routine manufacturing inspection, albeit only 2.2% of the injectors in Ozurdex Lot #E82852, contained particulate. Defendant also conducted a root cause investigation, which identified manufacturing issues, and implemented corrective action to eliminate "creation of the particle" during the manufacturing

process. Clearly, plaintiff's claim was based on more than the recall notice, and we reject defendant's arguments to the contrary.

The sufficiency of circumstantial evidence is a factual determination. See Moraca, 66 N.J. at 458. "If the proofs permit an inference that the accident was caused by some defect, whether identifiable or not, a jury issue as to liability is presented." Ibid. However, a plaintiff must present sufficient evidence the alleged product defect proximately caused her injuries. See Myrlak, 157 N.J. at 97. A jury must not be given circumstantial evidence about a product's alleged defect and then left to speculate. "The product itself must be of a type permitting the jury, after weighing all the evidence . . . to infer that in the normal course of human experience an injury would not have occurred . . . had there not been a defect attributable to the manufacturer." Scanlon, 65 N.J. at 593.

Plaintiff presented the testimony of Drs. Lalezary and Phillips, both of whom opined with a reasonable degree of certainty that the silicone particulate proximately caused her injury. Dr. Lalezary testified the silicone particulate was injected in plaintiff's eye and was a substantial factor in causing her blindness. He explained

> the particulate caused inflammation and traction in her peripheral retina that induced a retinal break and led to her retinal detachment. And subsequently, she had detachment repair that led to the anterior migration of

> the Ozurdex pellet. That compromised her vision because a patient with uveitis that develops a retinal detachment has a poor prognosis for recovery and vision.

Dr. Phillips testified the silicone particulate ultimately caused plaintiff to lose vision. He found

> what was interesting and remarkable in her case was the persistent inflammation, so that knowledge of the silicone particulate [from the recall] gave [him] a potential cause for why she was getting so much inflammation despite the fact that she still had the Ozurdex implant, which usually treated her inflammation fairly well. . . . Knowing that the silicone particulate could be there gave [him] at least a potential reason for the inflammation that wasn't responding to treatment.

According to Dr. Phillips, the particulate did not cause plaintiff's retina to detach because

> the detachment can occur spontaneously. It can occur just with the injection. . . . Where it could come into play as sort of affecting both would be from the inflammatory response. [T]here's really nothing unusual about retinal detachment. Those we treat every day, all the time. The corneal swelling, corneal specialists do corneal transplants for that all the time. The thing that was unusual in this particular instance for her was the amount of inflammation. So if I'm trying to tie the silicone particulate into anything, it's the inflammatory response that she had that persisted even long after the Ozurdex implant itself was gone.

The presence of the particulate was "the only thing that was different. [Plaintiff] had already had multiple injections before, and she'd even had surgery before . . . . So she had been through many procedures before and just never had this much inflammation, despite the fact that she does have uveitis."

We apply an abuse of discretion standard in review of a trial court's decision to admit expert testimony. In re Accutane Litig., 234 N.J. 340, 348 (2018). Summary judgment "is an extraordinary measure to be taken only with extreme caution, especially when a cause of action rests upon expert testimony." Kisselbach v. Cnty. of Camden, 271 N.J. Super. 558, 569 (App. Div. 1994). Even a "weak" medical report should be presented to a jury and if later found unreliable, may be subject to involuntary dismissal pursuant to Rule 4:37-2(b). Ibid.

"The net opinion rule is a 'corollary of [N.J.R.E. 703] . . . which forbids the admission into evidence of an expert's conclusions that are not supported by factual evidence or other data.'" Townsend, 221 N.J. at 53-54 (alterations in original) (citing Polzo v. Cnty. of Essex, 196 N.J. 569, 583 (2008)). An opinion that is "circular," or contains "bare conclusions, unsupported by factual evidence, is inadmissible." Buckelew v. Grossbard, 87 N.J. 512, 524 (1981). Experts must "give the why and wherefore that supports the opinion, rather than

a mere conclusion" and must "be able to identify the factual bases for their conclusions" and "explain their methodology." Townsend, 221 N.J. at 54-55 (quoting Borough of Saddle River v. 66 E. Allendale, LLC, 216 N.J. 115, 144 (2013), and Landrigan v. Celotex Corp., 127 N.J. 404, 417 (1992)). At its core, "[t]he net opinion rule is a 'prohibition against speculative testimony.'" Ehrlich v. Sorokin, 451 N.J. Super. 119, 134 (App. Div. 2017) (quoting Harte v. Hand, 433 N.J. Super. 457, 465 (App. Div. 2013)).

Dr. Lalezary is a Board-Certified Ophthalmologist and a Vitreo-Retinal Surgical Fellow, who has published on the topic of retinal detachment and is well versed in the applicable standard of care. His report recounted that he reviewed: plaintiff's medical records from her treating physicians, Drs. Phillips and Solomon; the deposition transcripts of plaintiff, Drs. Phillips and Solomon, and the associate vice president responsible for defendant's U.S. recalls; materials produced by defendants, including a Benefits-Risk Assessment and Field Alerts for Ozurdex; and the 2018 recall notice. Based on this information, the doctor opined with a "reasonable degree of medical certainty" that a silicone particulate was "unintentionally dispensed from the defective actuator" and that it "likely incited retinal detachment" which ultimately resulted in plaintiff's loss of vision.

Dr. Phillips also opined the particulate was the proximate cause of plaintiff's injury. He based his knowledge on: plaintiff's medical history and his treatment of her; the facts and circumstances surrounding the Ozurdex recall as it pertained to plaintiff; and the cause of plaintiff's loss of vision despite other potential causes.

Our difficulty is not with the theory of causation espoused by each expert or that causation could be established through a differential diagnosis. This is certainly permitted. See Creanga v. Jardal, 185 N.J. 345, 357-58 (2005). A physician is "not required to rule out all alternative possible causes of [the plaintiff's] illness. Rather, only 'where a defendant points to a plausible alternative cause and the doctor offers no explanation for why [the doctor] has concluded that was not the sole cause, that doctor's methodology is unreliable.'" Heller v. Shaw Indus., Inc., 167 F.3d 146, 156 (3d Cir. 1999) (quoting In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 758 n.27 (3d Cir. 1994)).

However, the issue here is the utter lack of evidence to support the existence of both general and specific causation. Plaintiff's experts' theory of causation is based on evidence that does not exist and would leave a jury to speculate whether there was ever a particulate in the applicator or particulate injected into plaintiff's eye.

There was no evidence the Ozurdex injection plaintiff received was defective and no evidence of a particulate in her eye. Defendant's experts disagreed the particulate would cause a detachment in her eye. The Retisert silicone insert, which was ten times larger than the alleged Ozurdex particulate, dislocated contemporaneously with her injury and could have been a cause of her injury. Plaintiff also had other underlying medical conditions that could have caused the injury, including: chronic eye inflammation, inflammation from smoking, and a history of ophthalmic procedure and intravitreal injections. For these reasons, the differential diagnosis was unavailing.

Lastly, our Supreme Court recently adopted the Daubert[7] factors to help guide trial courts to assess the reliability of scientific or technical expert testimony. State v. Olenowski, 253 N.J. 133, 149 (2023). Those factors are as follows:

> (1) Whether the scientific theory can be, or at any time has been, tested;
>
> (2) Whether the scientific theory has been subjected to peer review and publication, noting that publication is one form of peer review but is not a "sine qua non";
>
> (3) Whether there is any known or potential rate of error and whether there exist any standards for maintaining or controlling the technique's operation; and

[7] Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993).

> (4) Whether there does exist a general acceptance in the scientific community about the scientific theory.
>
> [In re Accutane, 234 N.J. at 398 (citing Daubert, 509 U.S. at 593-95).]

Aside from the lack of objective factual evidence of causation, there was no evidence presented by plaintiff's experts to convince us their theory of causation would pass muster under Daubert. The record is devoid of testing, error rates, peer reviews, publications, or general acceptance in the scientific community to support the method of causation in this case.

For these reasons, we are constrained to conclude the trial court should have barred plaintiff's experts because they did not establish general or specific causation. Defendant should have been granted summary judgment due to the lack of proof of causation. As summary judgment in defendant's favor was appropriate, we need not reach the arguments raised on the appeal regarding the denial of reconsideration.

Affirmed in part and reversed in part. We do not retain jurisdiction.